11/24/04

AF IRW

Attorney. Docket. No. 355492-2202
Application Serial No. 09/954,789

1617

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Charlie RICCI *et al.*

Title: METHODS FOR TREATING ENDOLEAKS DURING ENDOVASCULAR REPAIR OF ABDOMINAL AORTIC ANEURYSMS

Appl. No.: 09/954,789

Filing Date: 9/12/2001

Examiner: S. Sharareh

Art Unit: 1617

CERTIFICATE OF EXPRESS MAILING
I hereby certify that this correspondence is being deposited with the United States Postal Service's "Express Mail Post Office To Addressee" service under 37 C.F.R. § 1.10 on the date indicated below and is addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

EV 576615175 US (Express Mail Label Number)
November 22, 2004 (Date of Deposit)

Rene Campos (Printed Name)

(Signature)

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Appeal Brief is being filed in accordance with the provisions of 37 C.F.R. § 1.37 and authorization is hereby given to charge $340.00 to the undersigned deposit account 50-0872 to cover the fee required by 37 C.F.R. §1.17(c). If this fee is deemed to be insufficient, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 50-0872.

11/29/2004 HALI11 00000011 500872 09954789
01 FC:1402 340.00 DA

REAL PARTY IN INTEREST

The real party in interest in this application is MicroTherapeutics, Inc. (MTI), assignee of the entire right, title, and interest to this application by virtue of an assignment from the inventors to MTI in the grandparent application, U.S. Patent No. 6,203,779.

RELATED APPEALS AND INTERFERENCES

There are no related appeals and/or interferences relating to this application.

STATUS OF CLAIMS

Claims 1-19 were in the filed application.

Claims 1-15 were canceled with a preliminary amendment submitted with the filing of this application leaving Claims 16-19 as the only claims remaining in this application at that time.

Claim 16 was subsequently amended on July 15, 2002 in response to the Office Action mailed March 13, 2002. In addition, Claims 17-19 were canceled and new Claims 20-29 added.

Claim 16 was further amended on January 20, 2004 in response to the Office Action mailed October 21, 2003. In addition, new Claims 30-32 were added.

Claims 16 and 20-32 remain pending in the application and stands rejected under 35 U.S.C. 103(a) over McCrory (U.S. Patent No. 5,951,599), in view of Chuter *et al.* ((2000) *J. Vasc. Surg.* 31:122-33), May *et al.* ((2000) *J. Vasc. Surg.* 32:124-129) and Evans *et al.* (U.S. Patent No. 5,695,480), all of which are of record in the application.

This rejection of Claims 16 and 20-32 is appealed, herein.

A copy of the Claims on Appeal is provided as Appendix A.

STATUS OF AMENDMENTS

All amendments have been entered by the United States Patent and Trademark Office (herein, "the Patent Office").

SUMMARY OF INVENTION

As reflected by the title of this application, this invention relates to the repair of blood vessels and arteries. More specifically it relates to the amelioration of leaks which can occur when an aneurysm in a blood vessel or artery is being surgically repaired. Such vascular surgery is commonly referred to as "endovascular" surgery and the leaks sought to be sealed are referred to in the field as "endoleaks." Claim 16 is directed to a kit of parts for sealing these leaks and finds support in Appellants' specification at, for example, page 7, lines 26-29.

The first component of this kit is a fluid composition which forms a coherent mass in the presence of blood which mass adheres to the vascular surface and/or the surface of the endovascular prosthesis. This fluid comprises a biocompatible solvent and biocompatible polymer and is recited in Appellants' specification at, for example, page 8, lines 1-6.

The second component of this kit is a catheter suitable delivering the fluid composition to an endoleak site formed from endovascular repair of an aneurysm (specification at, e.g., page 8, line 7-8).

The third component is a catheter suitable for delivering an endovascular prosthesis to the aneurysm (page 8, lines 9-10).

The fourth component is an endovascular prosthesis comprising a *stent-graft*[1] capable of inhibiting but not completely arresting blood flow into the abdominal aortic aneurysm due to the presence of one or more endoleaks. Support for the fourth component of the kit can be found at, e.g., page 18, lines 1-14; page 25, lines 1-4 and 16-18; page 26, lines 15-19; and page 27, lines 8-10. However, it should be noted that the timing of this support in this application, and the applications from which it depends, is an issue in the instant Appeal, and is discussed at *I, infra.*

[1] Because of the relevance to the issue on Appeal, of the similar-looking terms *stent* and *stent-graft*, these terms will often appear in italics.

ISSUES

The primary issue for consideration by the Honorable Board of Patent Appeals and Interferences is whether to reverse or affirm the rejection of Claims 16 and 20-32 under 35 U.S.C. §103(a) over McCrory (U.S. Patent 5,951,599), in view of Chuter *et al.* ((2000) *J. Vasc. Surg.* 31:122-33), May *et al.* ((2000) *J. Vasc. Surg.* 32:124-129) and Evans *et al.* (U.S. Patent 5,695,480).[2] There is a subissue which concerns whether of not the Chutter and May references are available as prior art against these claims, in view of the disclosures in this application and its predecessors.

ARGUMENTS

Appellants respectfully submit that the outstanding obviousness rejection should be withdrawn for the following reasons:

I. The combination of the cited references (*i.e.*, McCrory, in view of Chuter *et al.*, May *et al.* and Evans *et al.*) can not render obvious the claimed invention because neither Chuter *et al.* nor May *et al.* constitute prior art. These articles each are predated by this application's "grandparent," which satisfies the written description requirement of 35 U.S.C. § 112, with respect to all of the claims on appeal, and in particular to their recitation of the use of *stent grafts.*

II. The combination of the cited references (*i.e.*, McCrory, in view of Chuter *et al.*, May *et al.* and Evans *et al.*) does not produce the claimed invention because:

[2] In the Office Action of April 1, 2004 at page 6, the Patent Office issued a new obviousness rejection over Evans *et al.* in view of Chuter *et al.* However, since Evans does not teach the use of stent-grafts (page 6) the new rejection relies on Chuter *et al.* to supply the alleged teaching that stents and stent-grafts are interchangeable. Accordingly, the arguments made, herein, with be equally applicable to the new obviousness rejection, which is based on only a subset of the references cited above.

A. Neither Chuter *et al.* nor May *et al.*, taken individually or together, establish that *stents* and *stent grafts* are interchangeable devices for endovascular repair; and

B. One skilled in the art would not be motivated to combine Chuter *et al.* and/or May *et al.* with McCrory.

These arguments are further discussed, below.

I. Neither Chuter *et al.* nor May *et al.* constitute prior art against the claimed invention

The instant application is a divisional of U.S. Patent Application Serial No. 09/528,656, now U.S. Patent No. 6,475,466, which, in turn, is a continuation-in-part of U.S. Patent Application Serial No. 09/273,120, now U.S. Patent No. 6,203,779. The '120 "grandparent" application has a filing date of March 19, 1999, which is prior to the publication dates of both the cited Chuter *et al.* and May *et al.* references, which were published in 2000.

The Patent Office alleges that Applicants are not entitled to the March 19, 1999 priority date of the grandparent application because "March 2000 is the earliest time the Applicants appear to have envisioned the use of stent-grafts in their kits"[3]. However, this assertion is incorrect. All of the claims under appeal find 35 U.S.C. § 112-satisfying support in the '120 application. The rejection concedes this support with respect to all aspects of these claims save their recitation of "stent grafts." Thus, a showing of support for these other aspects of the claimed invention need not be belabored.

The '120 application is drawn to methods of treating endoleaks during endovascular repair (see throughout, including the title). As described in the '120 specification, "[a]ny endoleak can be treated in the methods of this invention including endoleaks arising, for example, from incomplete sealing between the endovascular prosthesis and the aortic wall . . . " (column 4, lines 64-66). The specification further teaches that ". . . endovascular repair of such

[3] See, footnotes 1 and 2 bridging pages 2 and 3 of the Office Action of April 21, 2004.

aneurysms involves the introduction of an endovascular prosthesis into the abdominal aortic aneurysm which is an art recognized procedure described, for example, by Parodi[17]" (column 9, lines 34-37).

Parodi (reference 17, column 2, lines 13-16), in turn, recites in its very title "Endovascular AAA *Stent Grafts*: Technology, Training and Proper Patient Selection" (emphasis added) and describes the nature and use of *stent grafts*. This reference was incorporated by reference in its entirety into the '120 application.

Additionally, Example 2 of the '120 application describes the use of a Wallgraft (Schneider, Boston Scientific, Boston MA), which is a *stent-graft*. In fact, Example 2 described the use of Wallgraft that was intentionally perforated to produce a "graft defect" to demonstrate the efficacy of the particular described embodiment of the invention (see, *e.g.*, column 12, lines 46-48 and column 13, lines 22-27).

Accordingly, the '120 application, upon which the instant application is based, clearly contemplated the use of *stent-grafts* as an endovascular prosthesis. It is, therefore, incorrect for the Office to assert that the 1999-filed '120 application failed to contemplate *stent-grafts* in its kits.

Since the instant application is entitled to the 1999 filing date of the '120 application for the combination of each and every element of the kits claimed in claims 16 and 20-32, and since the filing date of the '120 application predates the Chuter *et al.* and May *et al.* references, they cannot constitute prior art against the claimed invention. Withdrawal of this rejection is, therefore, requested. As an aside, to this point in the prosecution of this application, there has been no request by the Examiner that any material from the Parodi article, which was incorporated by reference into the '120 specification, be directly recited in the present specification. If, in the opinion of the Honorable Board, this direct recitation would facilitate allowance of the claims, Appellants will be quick to oblige.

II. The combination of the cited references (*i.e.*, McCrory, in view of Chuter *et al.*, May *et al.* and Evans *et al.*) does not produce the claimed invention.

A. Neither Chuter *et al.* nor May *et al.*, taken individually or together, establish that stents and stent grafts are interchangeable devices for endovascular repair.

While, for reasons discussed above, the Chuter *et al.* and May *et al.* references are not available to support an obviousness rejection against the pending claims, there would be an independent reason to overturn the obviousness rejection based on these references, even if they were available.

The outstanding obviousness rejection[4] appears to rely on the combination of a U.S. Patent (*i.e.*, McCrory), which teaches vascular occlusive systems involving a *stent* and a polymeric composition; two clinical research studies (*i.e.*, Chuter *et al.* and May *et al.*), which report the clinical outcomes of endovascular aneurysm repair, involving stent-grafts, in populations of patients as allegedly teaching the equivalence of *stents* and *stent* grafts; and Evans *et al.*, a reference disclosing a kit for endovascular aneurysm repair.[5]

The rejection is improper because, neither Chuter *et al.* nor May *et al.*, taken separately or together, teach, suggest, or imply, that *stents* and *stent-grafts* are equivalent devices for endovascular repair. To the contrary, Chuter *et al.* at page 123 states that "[m]ost of the patients in this series underwent treatment with a custom-made *stent graft*, that consisted of two Z *stents* and a tubular, or tapered, sleeve of conventional fabric" (references omitted, emphasis added). The paper proceeds to discuss the particular characteristics of the *proximal stent* and *distal stent* (*Id.*), which comprise the stent-graft. This language affirmatively shows that, at least according

[4] Office Action of February 14, 2003 at page 2.

[5] For the purposes of this argument, the Evans reference will be ignored, since it was used by the Patent Office merely to show assemblage and use of a 'kit' for vascular repair (Office Action at page 3). Appellants submit that the combination of McCrory *et al.*, Chuter *et al.*, and May *et al.* do not produce the underlying invention claimed in "kit" form. Note that the Patent Office has conceded that Evans does not teach the use of stentgrafts (page 6).

to the Chuter *et al.* paper, stent-grafts *comprise* stents. Chuter *et al.* clearly do not teach that the *stent-grafts* are synonymous with, or equivalent to, *stents*.

The paper of May *et al.* appears to be drawn exclusively to the use of stent-grafts (using the terminology, "prosthetic devices"). The paper is replete with such terms as "graft-related," "graft failure," and "graft-related deaths" (*e.g.*, at page 127), while endovascular aneurysm repair using simple stents, without a graft component, does not appear to be within the scope of the clinical study.

Thus, the assertion by the Patent Office that one or both of these papers "teach that stent grafts and stents are interchangeably used in the art to treat vascular aneurysm" (Office Action at page 3), is simply incorrect. Such a teaching is not found in Chuter *et al.* and/or May *et al.* Not surprisingly, the Patent Office has failed to identify specific language in these references, to support of its conclusory assertion that Chuter *et al.* and/or May *et al.* teach that stents and stent-grafts are interchangeable (*Id.*).

Since the obviousness rejection relies on incorrect assertions relating to the alleged teaching in the clinical papers, Appellants submit that the Patent Office has failed to make a case for obviousness. For at least this reason, Appellants respectfully request withdrawal of the rejection.

B. One skilled in the art would not be motivated to combine Chuter *et al.* and/or May *et al.* with McCrory.

It is well-established patent law that to establish a *prima facie* case for obviousness, under 35 U.S.C. § 103, there must be (i) some suggestion or motivation to combine the references, (ii) a reasonable expectation of success, and (iii) the prior art must teach each and every limitation of the claims under examination. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991).

Therefore, even if, *arguendo*, the Chuter *et al.* or the May *et al.* references, taken separately or together, suggested that stents and stent-grafts were equivalent in the art, this observation, by itself, would be insufficient to support a prima facie obviousness rejection under *In re Vaeck.* To support an obviousness rejection in the instant case, Chuter *et al.* and May *et al.*, taken separately or together, must teach that *stent-grafts* are interchangeable with *stents* for use in endovascular aneurysm repair AND provide motivation to combine their teachings with the McCrory patent, which teaches vascular occlusive systems involving a stent and a polymeric composition. Only if both conditions are met could the resulting combination yield a method of endovascular aneurysm repair involving *stent-grafts* and polymeric compositions.

However, neither the Chuter *et al.* and/or the May *et al.* reference provides any motivation to be combined with the teachings of McCrory. Chuter *et al.* and May *et al.* are merely clinical studies involving populations of patients that underwent endovascular aneurysm repair, involving stent-grafts. The studies are almost purely descriptive and focus primarily on study methodology and statistical analyses, while providing little critical analysis of the underlying methods and devices used for endovascular repair.[6] Importantly, neither study appears to discuss polymeric compositions for use with stent-grafts; therefore, there is no logical nexus between the Chuter *et al.* and/or May *et al.* clinical studies and the invention disclosed in the McCrory patent.

Accordingly, there is no motivation to combine the references cited in support of the outstanding obviousness rejection. Under the standard set forth in *In re Vaeck*, discussed above, the Patent Office has failed to establish a *prima facie* case for obviousness for Appellants to rebut and the rejection should be withdrawn.

CONCLUSION

In view of the above arguments, Appellants submit that withdrawal of the outstanding obviousness rejection is in order. The rejection is factually/scientifically flawed because the contents of the Chuter *et al.* and/or May *et al.* references do not suggest that *stents* and *stent-grafts* are interchangeable devices. The rejection is legally flawed because, regardless of any inferences the Patent Office appears to have drawn from the clinical studies of Chuter *et al.* and/or May *et al.*, there is no motivation to combine these references with the teachings of McCrory. Lastly, the Patent Office has improperly asserted Chuter *et al.* and/or May *et al.* as prior art references when support for the pending claims is found in the ultimate parent application, which antedates the clinical studies cited as prior art references.

For at least these reasons, Appellants respectfully request withdrawal of the outstanding obviousness rejection.

Respectfully submitted,

Date Nov. 22, 2004 By _____

FOLEY & LARDNER LLP
Customer Number: 38706
Telephone: (650) 856-3700
Facsimile: (650) 856-3710

Stephen Todd
Attorney for Applicant
Registration No. 47,139

[6] Appellants do not intend to denigrate these clinical studies. Nonetheless, the concluding paragraphs of both studies (Chuter *et al.* at page 131 and May *et al.* at page 129) make self-evident the dearth of meaningful analysis contained within.

APPENDIX A: CLAIMS ON APPEAL

16. A kit of parts for use in sealing endoleaks arising from endovascular repair of an aneurysm which comprises:

(a) a fluid composition which forms a coherent mass in the presence of blood which mass adheres to the vascular surface and/or the surface of the endovascular prosthesis wherein said fluid composition comprises a biocompatible solvent and a biocompatible polymer;

(b) a catheter suitable for delivering the fluid composition to an endoleak site formed from endovascular repair of an abdominal aortic aneurysm;

(c) a catheter suitable for delivering an endovascular prosthesis to the aneurysm; and

(d) an endovascular prosthesis comprising a stent graft capable of inhibiting but not completely arresting blood flow into the abdominal aortic aneurysm due to the presence of one or more endoleaks.

20. The kit of parts according to Claim 16 wherein said biocompatible polymer is selected from the group consisting of cellulose acetate polymers, ethylene vinyl alcohol copolymers and polyacrylates.

21. The kit of parts according to Claim 20 wherein said biocompatible polymer is a cellulose acetate polymer or an ethylene vinyl alcohol copolymer.

22. The kit of parts according to Claim 16 wherein said biocompatible solvent is selected from the group consisting of dimethylsulfoxide, ethanol, ethyl lactate, and acetone.

23. the kit of parts according to Claim 22 wherein said biocompatible solvent is dimethylsulfoxide.

24. The kit of parts according to Claim 16 wherein the fluid composition further comprises a contrast agent.

25. The kit of parts according to Claim 24 wherein said contrast agent is a water insoluble contrast agent.

26. The kit of parts according to Claim 25 wherein said water insoluble contrast agent is selected from the group consisting of tantalum, tantalum oxide, tungsten, and barium sulfate.

27. The kit of parts according to Claim 25 wherein said water insoluble contrast agent is characterized by having an average particle size of about 10 μm or less.

28. The kit of parts according to Claim 24 wherein said contrast agent is a water soluble contrast agent.

29. The kit of parts according to Claim 28 wherein said water soluble contrast agent is selected from the group consisting of metrizamide, iopamidol, iothalamate sodium, iodomide sodium, and meglumine.

30. The kit of parts according to Claim 24 which further comprises:

(e) a contrast agent dissolved in saline.

31. The kit of parts according to Claim 30 wherein the contrast agent is iopamidol.

32. The kit of parts according to Claim 16 wherein said one or more endoleaks arises from incomplete sealing at the interface of the aortic wall and the end of the prosthesis or from defects within the endovascular prosthesis.